

MEDICAL CONTESTED CASE HEARING NO. 13058

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUE

A contested case hearing was held on February 5, 2013 to decide the following disputed issue:

Is the preponderance of the evidence-based medical evidence contrary to the decision of the Independent Review Organization that Claimant is not entitled to an anterior C5-6 disc replacement with decompression for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant appeared, and was assisted by Ombudsman BO; Carrier appeared, and was represented by Attorney JF.

BACKGROUND INFORMATION

Claimant sustained a compensable cervical injury, and described his symptoms as including numbness in the fingers of both hands. He has been diagnosed with a herniated disc, and agreed with Dr. B's recommendation for surgery.

KB, M.D., Claimant's surgeon, described Claimant's pathology, noting that the IRO incorrectly focused on Claimant's absence of radiculopathy; he testified that the IRO instead should have noted Claimant's diagnosis of myelopathy, which renders the proposed surgical procedure recommended by the ODG.

DISCUSSION

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011(22-a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence based medicine is further defined in Texas Labor Code Section 401.011(18-

a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, and outcome-focused, and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable. Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308(t), "[a] decision issued by an IRO is not considered an agency decision and neither the Department nor the Division [is] considered [a party] to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

With regard to a disc replacement, the ODG states as follows:

Under study, with recent promising results in the cervical spine, but not recommended in the lumbar spine. While comparative studies with anterior cervical fusion yield similar results, the expectation of a decrease in adjacent segment disease development in long-term studies remains in question. And there is an additional problem with the long-term implications of development of heterotopic ossification. Additional studies are required to allow for a "recommended" status. These should include an evaluation of the subset of patient who will most benefit from this procedure as well as study of advantages/disadvantages of disc design and surgical procedure in terms of outcomes (particularly for development of heterotopic ossification and adjacent segment disease). This recommendation is based on balancing what we know so far about the benefits and the risks for the patient. Adjacent segment disease seems to be a natural aging process, and ADR has not proven any benefit in altering that progression. The risks of heterotopic calcification associated with ADR may make it a sure way to end up with a solid fusion, and major risks also include potential revisions and technical learning curve issues with widespread use.

Overall Comparison to Fusion: Overall studies have demonstrated statistically significant non-inferiority of ADR vs. fusion with superior trending on many

outcomes but limited evidence of statistical superiority. This has persisted for longer-term follow-up (three to five years). Long-term studies have shown that necessity of adjacent-level surgery is similar in both the fusion and ADR groups along with similar rates of development of adjacent-segment disease. Complication rates are similar. Study quality is often severely limited with high dropout rates and there is no comparison to a non-surgical treatment. Neither treatment has been found to produce complete disappearance of symptoms. Return to work appears earlier in the ADR group but overall employment rate is not different at 2 years (including for a workers' compensation cohort) and 5 years. (Zechmeister, 2011) (Steinmetz, 2008) (Jawahar, 2010) (Kim, 2009) (Garrido, 2010) (Fekete, 2010) (Dettori, 2008) (Pointillart, 2001) (Cinotti, 1996) (Klara, 2002) (Zeegers, 1999) (Sekhon, 2003) (Sekhon, 2004) (Porchet, 2004) (Pimenta, 2004) (Sasso, 2007) (Heller, 2009) (Mummaneni, 2007) (Murrey, 2009) (Burkus, 2010) (ECRIb, 2009) (Tumialán, 2010) (Delamarter, 2010) (Kelly, 2011) See also the complete list, discussion, and rating of other Disc prosthesis references in the Fusion References Chapter.

Recommended Indications: The general indications for currently approved cervical-ADR devices (based on protocols of randomized-controlled trials) are for patients with intractable symptomatic single-level cervical DDD who have failed at least six weeks of non-operative treatment and present with arm pain and functional/ neurological deficit. At least one of the following conditions should be confirmed by imaging (CT, MRI, X-ray):

- (1) herniated nucleus pulposus;
- (2) spondylosis (defined by the presence of osteophytes); &
- (3) loss of disc height.

(Dettori, 2008)

At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement, whereas cervical radiculopathy is an inclusion criteria for the FDA investigations of cervical arthroplasties. (McAfee, 2004)

Decompression of nerve roots and/or the spinal canal is often the primary intervention that necessitates disc replacement with a goal of restoration of intervertebral disc and foraminal height to prevent recurrence of nerve root compression. Implant of a total disc requires intact ligaments, integrity of the facet joints, vertebral bodies with intact endplates and good bone quality. (Fekete, 2010) (Cepoiu-Martin, 2011)

Myelopathy: ADR is also recommended for myelopathy. The findings from two cohorts at two years postoperatively suggest that arthroplasty is equivalent to arthrodesis for the treatment of cervical myelopathy for a single-level abnormality localized to the disc space, but the study did not evaluate the treatment of

retrovertebral compression as occurs in association with ossification of the posterior longitudinal ligament. (Riew, 2008)

Recommended exclusions: Suggested exclusions include evidence of facet arthritis, spinal instability or significant deformity. While patients with myelopathy are suggested as candidates this is precluded if there is evidence of multilevel pathology or significant degeneration. Other suggested exclusions include the following:

- (1) axial neck pain as the solitary presenting symptom;
- (2) osteoporosis/ osteopenia;
- (3) spinal stenosis by hypertrophic spondyloarthrosis;
- (4) severe spondylosis (defined as bridging osteophytes, a loss of disc height greater than 50%, or absence of motion at less than 2%);
- (5) active infection;
- (6) material allergies;
- (7) presence of underlying comorbid disease such as HIV, hepatitis B or C, insulin-dependent diabetes, and/or autoimmune spondyloarthropathies such as rheumatoid arthritis; &
- (8) morbid obesity (BMI > 40).

As of yet there are no recommendations for precautions in terms of underlying psychiatric pathology, smoking history, current drug use history, workers' compensation status, or litigation status. (Auerbach, 2008) (Zechmeister, 2011) (Sasso, 2007)

Rationale for development of this treatment: It is generally suggested that mobility in a degenerate joint is the cause of pain. In the spine a problem arises as the mechanism of pain is incompletely understood. Proponents of artificial disc replacement point out that while there is evidence of a high success rate for anterior cervical discectomy and fusion (ACDF) for treatment of radiculopathy and myelopathy, the procedure is thought to increase biomechanical stresses at adjacent segments that may hasten degeneration. This concept is controversial as there is debate over whether this is a stand-alone phenomenon accompanying fusion or a part of natural history of degeneration. By maintaining adjacent level kinematics the rate of adjacent level degeneration is thought to lessen, although there is limited evidence to support this. Other proposed benefits include quicker return to normal employment and lifestyle and elimination of risks and morbidity with bone graft procurement. Pseudoarthrosis is also not a problem with disc replacement. (Phillips, 2005) (Auerbach, 2008) (Cepoiu-Martin, 2011) (Zechmeister, 2011)

Concerns with use: There is an increasing interest in spinal arthroplasty as an alternative to fusion in conjunction with cervical discectomy, but at this time there

are no comparative studies of ADR with other treatment modalities besides fusion. Longevity of this new procedure is unknown, which is important based on the targeted age of most patients who fit the current criteria for treatment (with a relatively young average age in workers' compensation patients). There is limited data in terms of mechanical failure and aseptic loosening. There is also limited evidence as to the long-term effect on index-level facet arthrosis and/or adjacent level degeneration/disease. It has been noted that the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus these devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007) Finally, the consequences of failure of an implant in close proximity to the spinal cord, the esophagus, and the trachea are of concern. Current literature suggests that an analysis of these types of questions will take from five to ten years.

Complications: Implant malposition, loosening, subsidence, implant migration, fractures and infection have all been reported and may necessitate retrieval and proceeding with an interbody fusion. Other reported complications include delayed fusion around the prosthesis, asymmetric endplate preparation resulting in postoperative kyphosis, and reduction in vertebral body height. The most common complications of both ADR and fusion are wound infections, dysphagia/dysphonia and allergic reactions. (Zechmeister, 2011) (Anderson, 2008) (Yi, 2010)

Adjacent segment degeneration and disease: Early studies of the Bryan disc vs. ACDF patients found non-significant difference in adjacent level surgery. The incidence of new symptomatic adjacent-disc disease in the TDR group was 1.3% vs. 13.9% in the ACDF group. A conclusion was that moderate or severe kyphosis was probably a contraindication for TDR as it produced significant decrease in subsequent motion and kyphosis might persist. (Robertson, 2005) While a 4-year study showed a 5% reoperation rate for adjacent level disease in the ADR group vs. 12% for the fusion group (not statistically significant) an 8-year follow-up found development in 19% of the ADR patients (four of 21). This appeared to be pre-existing. Spontaneous fusion occurred in 22% of cases (six patients) in the 8-year study. These authors suggested that their results were equivocal in supporting the theory that ADR reduced adjacent segment disease. (Garrido, 2010) (Quan, 2011) A recent comparison study found there was no significant difference between development of adjacent segment degeneration between ADR and fusion at a median follow-up of 37 months. The development is significantly higher in patients with concurrent DDD in the spine. Presence of osteopenia increases the risk. The authors also found that patients with concurrent lumbar spine degenerative disease also had a higher risk. (Jawahar, 2010) (Nunley, 2011) The

current predicted rate of development of adjacent segment disease after ACDF is 13.6% at five years and 25.6% at 10 years of follow-up. See also Adjacent segment disease/degeneration (fusion).

Heterotopic ossification (HO): (Defined as undesirable bone formation outside the skeleton after ADR that precludes the motion preservation for which the artificial discs were designed). An additional problem that has been published in the literature is development of heterotopic ossification. There appears to be a positive relationship between occurrence of HO and loss of movement of the cervical artificial disc, speculated to be due to bridging osteophyte formation. The effect of this on adjacent segment degeneration has yet to be determined but it is speculated that when this occurs at the intervertebral space it limits function of the disc and can possibly cause compression of the neural tissue. HO appears to increase with time, especially in bilevel procedures. One group of authors has gone so far as to indicate that HO is an inevitable postoperative complication. (Yi, 2010) A genetic predisposition has been suggested, and disc design appears to have an effect. Other contributing factors proposed include tissue trauma during surgery, surgical technique (including removal of bone dust), design allowing soft tissue or bony ingrowth to the disc space, osteolysis related to wear debris of metal on polyethylene component (in discs with this design), and use of nonsteroidal anti-inflammatories (for prophylaxis). (Yi, 2010) (Quan, 2011) Literature available is generally based on small subsets of IDE study patients, limiting power of the study and generalized interpretation. The incidence of HO after cervical TDR in the literature gives an upper range of as high as 76% for two-level procedures and 66% for single-level. A recent 8-year follow-up of the Bryan disc showed development in 48% of 27 operated segments with restricted range of motion in nine cases. Development was more likely in two-level procedures. In earlier studies HO was low-grade (less than grade 3), with the supposition that this is less likely to interfere with motion. Longer-terms studies have found development of HO at higher grades. Early studies found development to have little effect on outcome, with an explanation being that even in the worst case the functional result is similar to that of an interbody graft in an ACDF. In the 8-year study of the Bryan disc patients who developed HO findings showed a trend for slightly higher neck and arm pain analog scores (not statistically significant). (Quan, 2011) (Leung, 2005) (Heidecke, 2008) (Lee, 2010) (Tu, 2011) (Mehren, 2006)

Types of ADR devices: Cervical discs all share important characteristics including restoration of intervertebral disc height, allowing motion and decompression, with removal of disc material. Devices differ in terms of articulating surfaces (metal-on-metal or metal-on-plastic), and biomechanical properties (constrained, semi-constrained, or non-constrained).

Prestige Disc: On July 16, 2007 the FDA approved the Prestige® Cervical Disc System from Medtronic Sofamor Danek. (FDA, 2007) This is a two-piece prosthesis constructed of stainless steel, employing ball-in-groove articulation. In 2007 results were published of 541 patients with single-level disease enrolled in 32 sites comparing ADR replacement with the Prestige ST disc (276 patient) with ACDF (265 patients). Neurological success rate was significantly higher in the arthroplasty group at 24 months (92.8% vs. 84.3%, respectively) with similar success rates on other outcome measures. At the 24-month follow-up all joints in the treated group were mobile. Another comparison study at two years found no significant difference in clinical outcomes between ADR and fusion treated patients (AAOS, VAS, NDI, JOA, SF-36 and satisfactions scores). (Peng, 2011)

Bryan Disc: A single piece metal-on-polymer prosthesis (a later version of the Prestige disc). On 5/12/09, the FDA approved the Bryan Cervical Disc (Medtronic; Memphis, Tennessee) in patients who have failed at least 6 weeks of conservative therapy for intractable radiculopathy and/or myelopathy secondary to disc degeneration or herniation. In 2007 results were published comparing this disc to ACDF, the latter being considered “gold standard.” This was an FDA IDE trial. The results were limited to three sites (115 patients). At 24 months statistically significant improvement was found in the Neck Disability Index (NDI), the Neck Pain Score, and SF-36 Physical component scores. Arm pain relief was similar. The conclusion was that the prosthesis compared favorably. Two patients in both groups required ACDF for adjacent level disease. (Sasso, 2007) Later documentation, again reporting a 24-month follow-up, indicates this study was actually performed in 30 sites. Participants were now reported as 242 patients receiving the disc and 221 receiving an ACDF in this noninferiority trial. There was a 20% loss of patients following randomization (37 from the TDR group and 80 from ACDF). In addition, unblinding occurred as well as treatment crossover. Results showed a statistically significant decrease in both groups for NDI, with the ADR group showing a significantly improved score at 24 months (16.2 for disc and 19.2 for ACDF). Both of these scores fall into a moderate disability range. Neck pain score was significantly improved in the ADR group over ACDF scores (23 vs. 30.3, respectively). Arm pain was similar. Similar results were noted for SF-36, neurological success and return to work at 24 months. The ADR group returned to work earlier (41 day vs. 61 days). For the ADR group overall success rate was 80.4% vs. 71.8% for the ACDF group. (FDA, 2009) (Heller, 2009)

ProDisc-C: Constructed of two chromium-cobalt endplates with sagittal fins for fixation into the adjacent vertebral body and a fixed polyethylene core. In 2007 a limited study group (25 patients with cervical disc herniation) received either an ADR or ACDF. Segmental motion decreased in both groups, but was significantly

higher in the ACDF group. This study was only extended to six months. (Nabhan, 2007) In 2009 results were published in a 2-year follow-up of an IDE trial comparing the ProDisc-C (106) to ACDF in patients (103) from one of 13 investigational sites. There was no demographic measured for ongoing litigation or workers' compensation involvement, although pre-operatively 84.9% of the ACDF group and 82.5% of the TDR group were employed and at 24 months the numbers were 80% and 82.8%, respectively. In terms of medications approximately 48% of both groups were using schedule 2 and 3 drugs pre-operatively and this decreased to 13% in the fusion group and 11.2% of the TDR group. Results were similar in terms of VAS neck and arm pain and neurological success. Second surgeries were required by 8.5% fusion patients compared to 1.8% of TDR patients ($p=0.033$). Results show that at 24 months postoperatively, 84.4% of ProDisc-C patients achieved a more than or equal to 4 degrees of motion or maintained motion relative to preoperative baseline at the operated level. (Murrey, 2009)

Mobi-C: A prospective study of 76 patients with two-year follow-up has been published on this cervical disc. Of note, 85.5% of segments were mobile at 2 years. HO was stated as responsible for the fusion of 6/76 levels, but the presence of HO did not alter clinical outcome. Adjacent segment degeneration was found in 9.1% of patients. (Beaurain, 2009)

Study Designs: The general design the randomized controlled studies discussed is a non-inferiority design, one that is generally employed when a margin of inferiority for a new technology is accepted because it is offset by advantages (i.e. the new technology is less invasive or has lower cost). This is not the case for ADR. There are also problems with unblinding, high dropout rates, exclusion of patients after randomization and unclear or no intention-to-treat analysis. Non-validated instruments have been utilized for outcomes.

ADR in a workers' comp population: A subgroup analysis of workers' compensation patients in the IDE trials of the Prestige and Bryan cervical arthroplasties has been published. The study population included 93 patients out of 1,004 total (9.2%). Preoperatively, 36.2% of arthroplasty patients and 32.6% of fusion patients were working. The total number of study-group patients that were working preoperatively was not given. At 24 months, 63% of the arthroplasty patients and 53% of the ACDF patients had returned to work (non-significant intergroup difference). Again, the percentage of total study-group patients that returned to work was not given. Return to work was earlier for TDR patients (median of 101 days as compared to 222 days). This was not statistically significant when controlled for sex, study, and work status. As noted above in a Bryan disc study (the only comparison data available), the TDR total-study group

returned to work at 41 days vs. 61 days for the arthroplasty group. (Heller, 2009) Pre-operative work status was a significant factor for patients eventually working after surgery. While the arthroplasty group returned to work earlier as compared to the fusion group this was only significant for 3 months. It was noted that the increase in return to work in the TDR group could have been secondary to less disability in these patients. Details about work were not given (including full vs. limited duty). (Steinmetz, 2008)

Recent additional research: A recent technology assessment by the California Technology Assessment Forum (CTAF) recommended that cervical disc replacement does not meet CTAF criteria for improvement in health outcomes. A particular concern was that long-term outcomes were not available, particularly in terms of benefit in prevention of development of adjacent segment disease. (Walsh, 2010) In a review performed by Washington State Health Technology Clinical Committee published in 2009 findings showed that there were no statistical differences in pain relief or functional improvement between cervical ADR and fusion as measured at one to two years. Neurological success (defined to include maintenance and improvement in neurological function) was 78% for ADR and 67% for fusion (statistically significant). They noted that no cost studies have been performed. There was insufficient evidence to draw conclusions regarding safety and efficacy in populations outside those studied by the FDA. There was no mention of HO or adjacent segment disease. The cervical disc was approved when used for FDA indications at a single level and with no contraindications. (Dettori, 2008), The North American Spine Society evidence-based clinical guideline for treatment of cervical radiculopathy due to degenerative disorders suggested fusion and ADR were comparable treatments in the short-term for single level disease. They also noted that anterior cervical decompression was comparable to anterior fusion, producing similar clinical outcomes in the treatment of single-level cervical radiculopathy from degenerative disorders (grade of recommendation: B for both comparisons). (Bono, 2011)

See the Low Back Chapter for information on use in the lumbar region. For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

A review of Claimant's medical records, and a comparison of them with the criteria set forth in the ODG, shows that the proposed surgery is, indeed, a recommended treatment for Claimant's diagnosed cervical myelopathy, as shown by Claimant's CT myelogram of March 1, 2012.¹ Although the Petitioner has diagnosed Claimant with early myelopathy,² and the medical

¹ Claimant's Exhibit 6, pp. 1 and 2.

² Claimant's Exhibit 5, p. 4.

literature he has cited references the need for surgery in cases of moderate to severe myelopathy,³ the ODG makes no similar distinction,⁴ and states simply that the proposed surgery is . . . recommended for myelopathy. Given this evidentiary posture of the case, it is reasonable to conclude that the ODG, which is evidence-based, is contrary to the IRO's opinion, and that the surgical procedure in question should therefore be approved.

Even though all the evidence presented may not have been discussed in detail, it was considered; the Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:
 - A. On (Date of Injury), Claimant was employed by (Employer).
 - B. On (Date of Injury), Employer was self-insured for workers' compensation purposes.
 - C. Venue is proper in the (City) Field Office.
2. The Hearing Officer found the following facts:
 - A. Self-insured delivered to Claimant a single document stating the true corporate name of Self-insured, and the name and street address of Self-insured's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.
 - B. On (Date of Injury), Claimant sustained damage or harm to the physical structure of his body while he was within the course and scope of his employment with Employer.
 - C. The injury referenced in the previous Finding of Fact arose out of Claimant's employment with Employer.
 - D. An anterior C5-6 disc replacement with decompression is health care reasonably required for Claimant's compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.

³ Claimant's Exhibit 7, pp. 2 and 25.

⁴ Carrier's Exhibit D, p. 2.

2. Venue is proper in the (City) Field Office.
3. The preponderance of the evidence-based medicine is contrary to the decision of the Independent Review Organization that an anterior C5-6 disc replacement with decompression is not health care reasonably required for Claimant's compensable injury of (Date of Injury).

DECISION

Claimant is entitled to an anterior C5-6 disc replacement with decompression for his compensable injury of (Date of Injury).

ORDER

Carrier is liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the self-insured is the **(SELF-INSURED)**. The name and address of Self-insured's registered agent for service of process is:

**CT CORPORATION SYSTEM
350 NORTH ST. PAUL STREET
DALLAS, TEXAS 75201**

Signed this 11th day of February, 2013.

Ellen Vannah
Hearing Officer